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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,752

Applicant(s)

MARONEY ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because the language "disclosed" in line 1 is legal terminology and should be avoided. Correction is required. See MPEP § 608.01(b).

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate both stem and body. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is suggested to change "body" to --stem-- on page 11, line 25.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-27, 45-48, 50, 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46, 48, 50, and 52 are Markush type claims and must include the language "selected from the group consisting of".

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5. Claim 1 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 3, 9, 11, 12, 19, and 18, 19 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly has not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations. Claims 2-16 depend upon claim 1 and inherit all problems associated with the parent claim.

6. Claims 10-13 recite the limitation "said attaching step" in lines 5, 5, 1, and 1 respectively. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said attaching step" to recite --said securing step--.

7. Claim 17 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 7, 15, 22, and 21, 22 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly has not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations. Claims 18-27 depend upon claim 17 and inherit all problems associated with the parent claim.

8. Claim 45 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 3, 10, 12, 13, 20, and 19, 20 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly have not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations. Claim 46 depends upon claim 45 and inherits all problems associated with the parent claim.

9. Claim 47 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 7, 15, 22, and 21, 22 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly have not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations. Claim 48 depends upon claim 47 and inherits all problems associated with the parent claim.

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10. Claim 53 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 3, 11, 13, 14, 21, and 20, 21 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly have not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations.

11. Claim 54 recites the limitations "said resected bone" and "said final prosthesis assembly" in lines 8, 16, 23, and 22, 23 respectively. There is insufficient antecedent basis for these limitations in the claim. Resected bone and final prosthesis assembly have not been positively claimed in the body of the claim. It is suggested to change "said" to --a-- in the first appearance of the body of the claim for both limitations.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

12. Claims 45-48 and 53-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Farey (USPN 6,203,575 B1). Farey discloses a method of implanting a final prosthesis, which includes all limitations recited in the claims. Farey discloses a method (col.1, lines 35-53) comprising providing and positioning a trial assembly (6) in a resected bone (36), the trial assembly (6) including a trial body (7) having a trial body mating component (9), and a trial head having a trial head member (8) which includes a trial offset indicia (hole, 42, 43), and an eccentrically located (col.3, lines 57-60) trial head mating component (11) configured to mate with said body mating component (9, 10), rotating or moving the head (8) relative the body (7) in the resected bone (36) wherein the head (8) covers a resected surface (37) of the resected bone (fig.3, 6, 11; col.3, lines 62-64) and is at a user-selected orientation (col.1, lines 58-63), removing the trial

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assembly (6), positioning the trial assembly (6) in a scale mechanism (1), (col.1, line 49-50), where head offset indicia (42, 43) aligns with a value (H) on the scale mechanism (1), (col.5, line 41-col.6, line 2), securing or attaching a final head (4) to a final body (3) based on the value (col.5, lines 10-12) and implanting the final prosthesis (2) in the resected bone (36), (col.5, lines 12-17). Farey discloses body and head mating components (11, 9, 10) selected from the group consisting of a bore and a stem (col.3, lines 45-46).

13. Claims 28, 31-33, 35-37, 40-42, 44, 49-52, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Kummer et al. (USPN 5,910,171). Referring to claims 28, 36-37, 49-52, and 55, Kummer discloses a kit comprising a trial assembly including a trial body portion (11) having a trial bore (27) defined therein, a trial head portion (33) having a trial offset indicia (54, 50) and a fastener or an eccentrically located trial stem (41) extending from a head, the head stem configured to be received in a trial bore (fig.11), and a final prosthesis assembly including a final body portion (11) having a bore (27) defined therein, a final head portion (33) having a final head member and offset indicia (54), and an eccentrically located (col.3, lines 15-18) final head stem (41) extending from a head portion the head stem being configured to be received within a bore (fig.11). Kummer discloses modular stem and head components (col.2, lines 61-64) and it is inherent that some are trial and some are final components.

Referring to claims 31 and 40, Kummer discloses a trial body (11) having internal threads within bore (27), and a head (33) having an external thread fastener (41) in a head passageway (51), the external threads (fig.12-15) configured to engage internal bore threads (col.8, lines 45-60).

Referring to claims 32 and 41, Kummer discloses a final head stem (41) having a male taper, a final body having a female tapered bore (27), the stem secured in the bore in a friction fit manner (col.7, lines 27-37; col.5, lines 4-11).

Referring to claims 33 and 42, Kummer discloses a trial body (11) having a body stem (13), a neck (fig.2), and a flat (23), wherein a bore extends through flat and neck (fig.11; col.4, lines 24-25).

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Referring to claims 35 and 44, Kummer discloses a trial and final body portion configured to be advanced into a humerus (col.4, lines 11-13).

14. Claims 49-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Huebner (USPN 6,102,953). Referring to claims 49-52 and 55, Huebner discloses a kit (fig.2; col.2, lines 51-52) comprising a trial assembly (10) including a trial body portion (18, 218) having a trial body mating component (222, 84), a trial head portion (12, 212) having a trial offset indicia (108, 226) an eccentrically located head mating component or fastener (82, 226) configured to mate with the body mating component, and a final prosthesis assembly including a final body portion (18, 218) having a body mating component (222, 84), a final head portion (12, 212) having a final head member and offset indicia (108, 226), and an eccentrically located head mating component (82, 226) configured to mate with the body mating component. Huebner discloses mating component selected from the group consisting of a bore and a stem (fig.3, 23). Huebner discloses modular stem and head components (fig.2; col.7, lines 36-54) and it is inherent that some are trial and some are final components.

15. Referring to claims 53-54, Huebner discloses a method of implanting a final prosthesis comprising providing and positioning a trial assembly (10) in a resected bone, the trial assembly (10) including a trial body (18, 218) having a trial body mating component (222, 84), and a trial head having a trial head member (12, 212) which includes a trial offset indicia (108; col.7, lines 42-43), and an eccentrically located trial head mating component (226, 82) configured to mate with said body mating component, rotating or moving the head relative to the body (col.8, lines 18-23), wherein the head covers a resected surface of the resected bone and is at a user-selected orientation, removing the trial assembly, positioning the trial assembly in a scale mechanism, where head offset indicia aligns with a value on the scale mechanism, securing or attaching a final head to a final body based on the value and implanting the final prosthesis in the resected bone (col.7, lines 36-54).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-2, 5-9, 11-17, 20-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farey (USPN 6,203,575 B1). Farey discloses a method of implanting a final prosthesis substantially as claimed. Referring to claims 1, 9, and 17, Farey discloses a method (col.1, lines 35-53) comprising providing and positioning a trial assembly (6) in a resected bone (36), the trial assembly (6) including a trial body (7) having a body mating component (9), and a trial head having a trial head member (8), and an eccentrically located (col.3, lines 57-60) trial head mating component (11) configured to mate with said body mating component (9, 10), a final head portion (4), and an eccentrically located final head mating component (11), rotating or moving the trial head (8) relative the trial body (7) in the resected bone (36) wherein the head (8) covers a resected surface (37) of the resected bone (fig.3, 6, 11; col.3, lines 62-64) and is at a user-selected orientation (col.1, lines 58-63). Farey discloses an offset indicia on a trial and final head portion (marking, col.4, line 64). Farey discloses removing the trial assembly (6), positioning the trial assembly (6) in a scale mechanism (1), (col.1, line 49-50), where head surface indicia aligns with a value (H) on the scale mechanism (1), (col.4, lines 63-66; col.5, line 41-col.6, line 2), securing or attaching a final head (4) to a final body (3) based on the value (col.5, lines 10-12) and implanting the final prosthesis (2) in the resected bone (36), (col.5, lines 12-17). Farey discloses body (9, 10) and head mating components (11) selected from the group consisting of a bore and a stem (col.3, lines 45-46). Farey discloses the claimed invention except for discloses a bore (11) in the head (4, 8) instead of the body (3, 6) and a stem (9, 10) in the body (3, 6) instead of the head (4, 8). It would have been obvious

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to one having ordinary skill in the art at the time the invention was made to have a bore in the body and stem in the head since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Referring to claims 2 and 13, Farey discloses securing the trial and final head to the trial and final body respectively when head and body portions are aligned (fig. 3, 6, 11, 9, 10, 13).

Referring to claims 5-8, 11-12, 14, 20-23, and 25, Farey discloses a scale mechanism (1) including an indicia surface (20) possessing markings, which depict a clock divided into a plurality of sections (fig. 9, 12, 14) and an identified value (H) on one of plurality of sections, and positioning a trial and final head portion adjacent to the indicia surface (fig. 12, 14; col. 4, lines 58-61). Farey discloses a scale mechanism (1) including a channel (21, 17) and locating a body portion within the channel.

Referring to claims 16 and 27, Farey discloses a resected humerus bone (36).

Referring to claims 15 and 26, Farey discloses surface indicia on a head portion of a prosthesis (col. 4, line 64) in the form of a marking. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a removable sticker or notch in place of a marking because applicant has not disclosed that a removable sticker or notch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a marking because all perform to visually indicate a position. Therefore, it would have been an obvious matter of design choice to modify Farey to obtain the invention as specified in claims 15 and 26.

18. Claims 3-4, 10, 18-19, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farey (USPN 6,203,575 B1) in view of Kummer et al. (USPN 5,910,171). Farey discloses a trial body and final body having bore and stem mating component substantially as claimed and explained above. Farey does not disclose however, internal threads within a bore located at a neck and flat, external threads on a fastener, a tapered male head stem, or a tapered body bore. Kummer teaches in the same field of

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endeavor, a trial and final (modular; col.) body and head, the body having a neck and flat with a bore (27) there through, the bore (27) being tapered (fig. 11) or having threads (fig. 12-15), and a head (33) having a stem (41) that is tapered (fig. 6, 11) or threaded (fig. 12-15), in order to provide a secure attachment or friction fit between the head and body components (col. 5, lines 5-12; col. 8, lines 40-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kummer's teaching of tapered or threaded attachment in head and body components, with Farey's head and body components, in order to provide a secure attachment or a friction fit.

19. Claims 29-30 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kummer et al. (USPN 5,910,171) in view of Farey (USPN 6,203,575 B1). Kummer discloses a kit comprising trial and final prosthesis components substantially as claimed and explained above. Kummer does not disclose however, a scale mechanism having a channel, a surface indicia, markings on a surface indicia, and sections possessing values indicated thereon. Farey teaches in the same field of endeavor a kit having trial and final prosthesis components along with a scale mechanism (1). Farey teaches a scale mechanism (1) having an indicia surface (20) configured to position adjacent a head portion, the indicia surface having markings depicting a clock, divided into sections with values (fig. 9, 12, 14) and a channel (21, 17) configured to receive a body portion, in order to record an optimal position of a trial prosthesis and replicate the position into a final prosthesis for implantation (col. 3, lines 23-31; col. 4, lines 23-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Farey's teaching of a scale mechanism with the mechanism particulars used with trial and final prosthesis components, with Kummer's trial and final prosthesis components, in order to record an optimal position of a trial prosthesis and replicate the position into a final prosthesis for implantation.

20. Claims 34 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kummer et al. (USPN 5,910,171). Kummer discloses a kit having a trial and final head portion of a prosthesis having a surface indicia (54) substantially as claimed and explained above. Kummer has shown in fig. 12 a surface

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indicia (54) being a notch. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a removable sticker in place of a notch because applicant has not disclosed that a removable sticker provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a notch because both perform to visually indicate a position. Therefore, it would have been an obvious matter of design choice to modify Kummer to obtain the invention as specified in claims 34 and 43.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

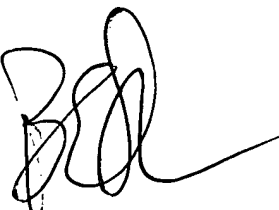
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

September 17, 2002



BRUCE SNOW
PRIMARY EXAMINER